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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/729,807	12/05/2003	Olga Bandman	PF-0651-1 DIV	3257

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EXAMINER	
SWOPE, SHERIDAN	

ART UNIT	PAPER NUMBER
1652	

DATE MAILED: 07/22/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/729,807	BANDMAN ET AL.	
	Examiner	Art Unit	
	Sheridan L. Swope	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-7 and 9-29* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-7 and 9-29* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Applicant's Preliminary Amendment of December 5, 2003 is acknowledged. It is acknowledged that Claims 8 and 30-91 have been cancelled. Claims 1-7 and 9-29 are pending.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121 ~~and 372~~:

I. Claims 1, 2, 17, and 18, drawn to a protease polypeptide, classified in class 435, subclass 226.

II. Claims 3-7, 9, 10, 12, and 13, drawn to a polynucleotide encoding a protease, vectors, host cells, and methods of making the protease, classified in class 435, subclass 325.

III. Claim 11, drawn to an antibody to a protease, classified in class 530, subclass 388.26.

IV. Claims 28, in part, 14, 15, and 29, drawn to a method of detecting, by hybridization, a polynucleotide encoding a protease, classified in class 435, subclass 6.

V. Claims 28, in part, 16, drawn to a method of detecting, by amplification, a polynucleotide encoding a protease, classified in class 435, subclass 6.

VI. Claim 19, drawn to a method of treatment using a protease, classified in class 424, subclass 94.63.

VII. Claims 20, 23, and 27, drawn to a method of screening for a modulator of a protease, classified in class 435, subclass 23.

VIII. Claim 21, drawn to an agonist of a protease, which can be a protein, nucleic acid, carbohydrate, or any other compound or composition, classified in class 530, subclass 300, class 536, subclass 23.1, or class 536, subclass 1.11.

IX. Claim 22, drawn to a method of treatment using an agonist of a protease, classified in class 514, subclass 1.

X. Claim 24, drawn to an antagonist of a protease, which can be a protein, nucleic acid, carbohydrate, or any other compound or composition, classified in class 530, subclass 300, class 536, subclass 23.1, or class 536, subclass 1.11.

XI. Claim 25, drawn to a method of treatment using an antagonist of a protease, classified in class 514, subclass 1.

XII. Claim 26, drawn to method of screening for a compound that binds to a protease, classified in class 435, subclass 23.

For each of inventions I-XII above, restriction to one of the following is also required under 35 USC 121 and 327. Therefore, election is required of one of inventions I- XII and one of inventions (A)-(P).

(A). SEQ ID No: 19 or a sequence encoding SEQ ID No: 1.

(B). SEQ ID No: 20 or a sequence encoding SEQ ID No: 2.

(C). SEQ ID No: 21 or a sequence encoding SEQ ID No: 3.

(D). SEQ ID No: 22 or a sequence encoding SEQ ID No: 4.

(E). SEQ ID No: 23 or a sequence encoding SEQ ID No: 5.

(F). SEQ ID No: 24 or a sequence encoding SEQ ID No: 6.

(G). SEQ ID No: 25 or a sequence encoding SEQ ID No: 7.

(H). SEQ ID No: 26 or a sequence encoding SEQ ID No: 8.

(I). SEQ ID No: 27 or a sequence encoding SEQ ID No: 9.

(J). SEQ ID No: 28 or a sequence encoding SEQ ID No: 10.

(K). SEQ ID No: 29 or a sequence encoding SEQ ID No: 11.

(L). SEQ ID No: 30 or a sequence encoding SEQ ID No: 12.

(M). SEQ ID No: 31 or a sequence encoding SEQ ID No: 13.

(N). SEQ ID No: 32 or a sequence encoding SEQ ID No: 14.

(O). SEQ ID No: 33 or a sequence encoding SEQ ID No: 15.

(P). SEQ ID No: 34 or a sequence encoding SEQ ID No: 16.

(Q). SEQ ID No: 35 or a sequence encoding SEQ ID No: 17.

(R). SEQ ID No: 36 or a sequence encoding SEQ ID No: 18.

The inventions are distinct, each from the other because of the following reasons:

Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). Also, product and process inventions are distinct if any of the following can be shown: (1) that the process as claimed can be used to make another and materially different product, (2) that the product claimed can be used in a materially different process of using that product, or (3) that the product claimed can be made by another and materially different process (MPEP § 806.05(h)). These inventions are different or distinct for the following reasons.

Inventions (A)-(R) are distinct because they represent structurally different polypeptides and the polynucleotides encoding them. Therefore, where structural identity is required, such as for hybridization or expression, the different sequences have different effects.

The nucleic acid of Invention II is related to the protein of Invention I by virtue of encoding the same. The DNA molecule has utility for the recombinant production of the protein in host cells, as recited in Claim 9. Although the DNA molecule and protein are related, since the DNA encodes the specifically claimed protein, they are distinct inventions because they are physically and functionally distinct chemical entities, and the protein product can be made by another and materially different process, such as by synthetic peptide synthesis or purification from the natural source. Further, the DNA may be used for processes other than the production of the protein, such as nucleic acid hybridization assay.

The protein of Invention I is related to the antibody of Invention III by virtue of being the cognate antigen necessary for the production of antibody. Although the protein and antibody are related, due to the necessary steric complementarity of the two, they are distinct inventions because they are physically and functionally distinct chemical entities and because the protein can be used in another and materially different process from the use for production of the antibody, such as in a pharmaceutical composition in its own right or in assays for the identification of agonists or antagonists of the enzyme.

The protein of Invention I is related to the agonist and antagonist of Inventions VIII and X, respectively, by virtue of being the cognate enzyme regulated by the agonist and antagonist. Although the protein is related to the agonist and antagonist, due to the necessary steric complementarity of the two, they are distinct inventions because they are physically and

functionally distinct chemical entities and because the protein can be used in another and materially different process from the use for identification of the agonist and antagonist, such as in a pharmaceutical composition in its own right or preparation of an antibody, while the agonist and antagonist can be used to purify the polypeptide.

Invention II is unrelated to Inventions III, VIII, and X because the polypeptide of Invention I is a physically and functionally distinct chemical entity from the products of Inventions III, VIII, and X.

Invention III is unrelated to Inventions VIII and X because the antibody of Invention III is a physically and functionally distinct chemical entity from the products of Inventions VIII and X.

Inventions VIII and X are unrelated because the products of said inventions are physically and functionally distinct chemical entities

Inventions IV-VII, IX, XI, and XII are independent because the methods of Inventions IV-VII, IX, XI-XII comprise different steps, utilize different products and/or produce different results.

Inventions IV and V unrelated to Inventions I, III, VIII, and X because the methods of Inventions IV and V can neither use the products of Inventions I, III, VIII, and X nor be used to make said products.

Invention VI is unrelated to Inventions II, III, VIII, and X because the method of Invention VI can neither use the products of Inventions II, III, VIII, and X nor be used to make said products.

Invention VII and Invention II are unrelated because the method of Invention VII can neither use the product of Invention II nor be used to make said product.

Invention IX is unrelated to Inventions I-III and X because the method of Invention IX can neither use the products of Inventions I-III and X nor be used to make said products.

Invention XI is unrelated to Inventions I-III and VIII because the method of Invention XI can neither use the products of Inventions I-III and VII nor be used to make said products.

Invention XII is unrelated to Inventions II, VIII and X because the method of Invention XII can neither use the products of Invention VIII and X nor be used to make said products.

The methods of Inventions IV and V are related to the polynucleotide of Invention II as a product and process of using. The Inventions are distinct because the polynucleotide can also be used for making the encoded protein.

The methods of Invention VI are related to the proteins of Invention I as a product and process of using. The inventions are distinct because the protein can also be used for making an antibody.

The methods of Invention VII are related to the protein, agonist, and antagonist of Inventions I, VIII, and X, respectively, as a products and process of using. The inventions are distinct because the protein, agonist, and antagonist can also be used for making an antibody.

The methods of Invention IX are related to the agonist of Invention VIII as a products and process of using. The inventions are distinct because agonist can also be used for making an antibody.

The methods of Invention XI are related to the antagonist of Invention X as a products and process of using. The inventions are distinct because antagonist can also be used for making an antibody.

The methods of Invention XII are related to the polypeptide and antibody of Inventions I and III as a products and process of using. The inventions are distinct because the polypeptide can be used for production of the antibody and the antibody can be used for immunocytochemistry.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art due to their recognized divergent subject matter, as shown by their different classification, restriction for examination purposes as indicated is proper.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the Official Gazette notice dated March 26, 1996 (1184 O.G. 86; see also M.P.E.P. 821.04, *In re* Ochiai, and *In re* Brouwer). Process claims that depend from or otherwise include all the limitations of the patentable product will be entered as a matter of right, if the amendment is presented prior to final rejection or

allowance, whichever is earlier. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. To be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sheridan L. Swope whose telephone number is 571-272-0943. The examiner can normally be reached on M-F; 9:30-6 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy can be reached on 571-272-0928. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Sheridan Lee Swope, Ph.D.